UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,689	03/25/2004	Mark Larche	JKJ-005CNRCE2	7876

959 7590 06/22/2010

LAHIVE & COCKFIELD, LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,689	LARCHE ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 16-29* is/are pending in the application.

4a) Of the above claim(s) *16-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/09/2009 has been entered.

2. Claims 1-5 and 16-29 are pending.

3. Claims and 16-29 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Claims 1-5 are currently under examination as they read on a method of desensitizing a patient to a polypeptide allergen comprising administering to the patient a peptide wherein restriction to DR4 possessed by the patient can be demonstrated for the peptide and the peptide is able to induce a late phase response in an individual who possesses DR4.

5. Acknowledgment is made of receipt of the certified copies of the United Kingdom 9800445.0 and 9820474.6 applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The claims are missing the steps of:

determining MHC Class II restriction of the individual; and

determining what peptides induces a late phase response.

The Examiner suggests that Applicant includes these screening steps in the method. As it stands the claims recite function without structure (ability to induce a late phase reaction, binds to MHC Class II DR molecules, etc.). It is suggested that the claims be amended to recite the steps associated with determining the structures instead of simply reciting them as a limitations of the claims.

The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

8. Claims 1-5 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention for the same reasons as set forth in the Office action mailed on 03/28/2007.

Applicant is in possession of: the peptides of SEQ ID NO: 1, SEQ ID NO:2 and SEQ ID NO:3 for stimulating T cells in vitro.

Applicant is not in possession of: a method of inhibiting an allergic reaction to a polypeptide allergen in an individual comprising: (a) **selecting a peptide from the allergen for its ability to induce a late phase reaction;** and (b) administering to the individual patient the **selected peptide** from the allergen, wherein (i) **the selected peptide is able to bind a particular restriction to a MHC Class II molecule possessed by the individual, (ii)** the selected peptide has a length of 5 to 50 amino acids and (iii) the polypeptide allergen is selected from the group consisting of SEQ ID NO's:19-31, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO's:38-86, and SEQ ID NO's:88-124 of claim 1; wherein **the peptide** is included in a composition containing **a plurality of peptides** of claim 2; wherein the **plurality of peptides** includes **a peptide which binds to a MHC molecule selected from the group consisting of DR2, DR3, DR4 and DR7** of claim 3; wherein the individual possesses MHC Class II DR molecule selected from the group consisting of DR2, DR3, DR4 and DR7 of claim 4; and wherein the individual possesses the

MHC Class II molecule DR4 of claim 5 for the same reasons as set forth in the Office Action mailed on 06/09/2009.

Applicant's arguments filed on 12/09/2009 have been fully considered, but are not found persuasive.

Applicants argue that

"The Examiner has maintained that the specification does not show that the inventors possessed the invention at the time of filing, in particular due to the lack of an adequate correlation between function and structure. As discussed above, Claim 1 has been amended to disclose that the selected peptide is derived from a discrete number of defined polypeptide allergens comprising an amino acid sequence selected from the group consisting of SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124. Applicants respectfully submit that the genus of peptides claimed for use is now limited to those of a defined length selected from a defined list of allergen sequences. The specification at page 50, line 2 to page 81, line 2 clearly describes this genus and so provides an adequate disclosure of the structural properties of the peptides.

Furthermore, the specification also teaches how peptides of this structural genus may be correlated with the function of inducing a late phase reaction and used to inhibit allergic reactions. The specification in particular provides a description of how peptides selected structurally from allergen proteins may be tested to identify those able to induce a late phase reaction (Example 6, as discussed above). Applicants respectfully submit that this teaching clearly indicates that Applicants were in possession of the claimed genus at the time of filing. The necessary correlation between structure and function required to adequately describe the genus is provided by the specific peptide allergen sequences recited in the claims and the functional language with respect to late phase reactions. As discussed above, the Examples show that peptide sequences from allergen sequences which have been selected in this manner are able to inhibit allergic reactions.

The Examiner also commented that the disclosure of the necessary screening method did not necessarily lead to the genus of peptides. In particular, the case of *Univ. Of Rochester V.G.D Searle & Co., Inc.,* 358F.3d916, 69 USPQ2d 1886 (fed.Cir.2004) is highlighted. An important distinction over the facts of that case is that the present invention does provide a working example in which peptides (SEQ ID NOs: 1 to 3) possessing the claimed structure and function are demonstrated to inhibit allergic reactions.

The present application does not, therefore, merely disclose assays for screening peptides, but provides specific peptides selected by such assays which are then shown to have the necessary inhibitory property. Applicants submit that this disclosure of specific and concrete peptides having the same properties as the claimed genus of peptides leads to an adequate written description.

Thus, the teaching provided in the present invention in relation to specific peptides can be distinguished over the situation of *Univ. Of Rochester V.G.D Searle & Co., Inc.,* where no such disclosure of any compounds used in the claimed methods was present. The members of the claimed genus are also not selected at random from a variety of different substances, but have the common feature that they are all peptides of 5 to 50 amino acids in length, able to bind to a particular MHC Class II and being from allergens defined by specific amino acid sequences (i.e. SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124). Applicants respectfully submit that the exemplification of particular peptides having these features (i.e. SEQ ID NOs 1 to 3) indicates clear possession of the genus of peptides having these features.

It remains the Examiner's position that the specification has not adequately described a correlation between function (inhibiting an allergic reaction, induce a late phase reaction, binds to a particular MHC Class II molecule, binds to a MHC Class II DR molecule selected from the group consisting of DR2, DR3, DR4 and DR7) and structure responsible for inhibiting an allergic reaction, inducing a late phase reaction, binds to a particular MHC Class II molecule, induces late phase response, and binds to a MHC Class II DR molecule selected from the group consisting of DR2, DR3, DR4 and DR7 such that one of ordinary skill in the art would have known what peptides encompassed by claims could be generated to have the disclosed functions. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features See University of Rochester, 358 F.3d at 927, 69 USPQ2d at 1895. "Without a correlation between structure and function, the claims do little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement." Ex parte Kubin, 83 U.S.P.Q.2d 1410 (BPAI 2007). The specification does not adequately describe the genus of 5 to 50 amino acid peptides for use in the claimed method for inhibiting an allergic reaction and inducing a late phase response which bind to DR2, DR3, DR4 and DR7 MHC Class II molecules.

Applicant's argument that specific peptide allergen sequences recited in the claims and the functional language with respect to late phase reactions is sufficient is not persuasive. The structures recited in the claims do not possess the recited functions. The structures recited in the

claims are the starting materials to determine which peptides of those starting materials possess the claimed functions.

Applicant's argument that the instant case is distinguished over University of Rochester because the instant specification provides a working example is not persuasive. The description of peptides that have the claimed functions in the specification is not sufficient to describe the extremely large genus of peptides encompassed by the instant claim recitations. One of ordinary skill in the art would not be able to determine which peptides are encompassed for use in the instant method.

A screening method is provided in the instant applicant for identification of peptides which bind to a MHC Class II DR molecule and have the ability to induce a late phase responses. While discoveries may allow the development of screening assays to identify peptides, the test peptide themselves, have not yet been developed. The instant claims are designed to cover the use of the peptides prior to identification of the peptide themselves.

As stated supra with respect to the rejection of 112, second paragraph, it is the Examiner's position that Applicant should amend the claims to recite the actual method steps necessary to screen for structures having those functions instead of reciting the functions only as functional language.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 21, 2010

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644